

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)
)
)
THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8403

Bartle, C.J.

February 22, 2010

Vaughn Brotton ("Mr. Brotton" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Morris Drabinsky, M.D., F.A.C.C., F.C.C.P. Based on an echocardiogram dated May 30, 2001, Dr. Drabinsky attested in Part II of claimant's Green Form that he suffered from severe aortic regurgitation.³ Based on this finding, claimant would be

2. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. Dr. Drabinsky also attested that claimant suffered from mild mitral regurgitation and an ejection fraction in the range of 50% to 60%. These conditions, however, are not at issue in this

(continued...)

entitled to Matrix A-1,⁴ Level I benefits in the amount of \$92,786.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Christakis Christodoulous, M.D., observed that claimant suffered from "[m]ild aortic stenosis with bicuspid valve." Dr. Drabinsky, however, attested that claimant did not have congenital aortic valve abnormalities, that is, claimant did not have a unicuspida, bicuspid, or quadricuspid aortic valve or a ventricular septal defect associated with aortic regurgitation. Under the Settlement Agreement, the presence of one of these congenital aortic valve abnormalities requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)a). As the Trust does not contest Mr. Brotton's entitlement to Level I benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or B-1.

3. (...continued)
claim.

4. Although claimant indicates in Part I of the Green Form that he is seeking Level II benefits, Part II of the Green Form does not present any of the complicating factors necessary to receive Matrix Benefits for damage to the aortic valve. See Settlement Agreement § IV.B.2.c.(2)(a).

5. Under the Settlement Agreement, a claimant is entitled to Level I benefits for damage to the aortic valve if he or she is diagnosed with severe aortic regurgitation. See Settlement Agreement § IV.B.2.c.(1)(a).

In November 2002, the Trust advised Mr. Brotton that his claim was selected for audit.⁶ In response, claimant submitted a letter from Dr. Drabinsky, who stated, in pertinent part, that "[w]hile the aortic valve commissures appear fused, this is not a bicuspid aortic valve." (Emphasis in original.)

In January 2003, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that claimant's aortic valve was bicuspid and that there was no reasonable medical basis for Dr. Drabinsky's representation as to the absence of congenital aortic valve abnormalities. In support of this finding, Dr. Churchwell explained that the "[a]ortic valve is bicuspid with heavy calcium on non-coronary cusp."⁷

6. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, the auditing cardiologist was asked to review claimant's level of aortic regurgitation, level of ejection fraction, and whether claimant suffered from congenital aortic valve abnormalities or aortic stenosis. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

7. Dr. Churchwell also confirmed that claimant suffered from severe aortic regurgitation and did not suffer from aortic stenosis. Dr. Churchwell, however, found that claimant's ejection fraction was in the range of 60% to 70% and concluded that there was no reasonable medical basis for Dr. Drabinsky's

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Based on the auditing cardiologist's determination that claimant's aortic valve was bicuspid, the Trust issued a post-audit determination finding that Mr. Brotton was entitled only to Matrix B-1, Level I benefits. Pursuant to the Audit Policies and Procedures, claimant contested this determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and Procedures § IV.C.⁸ The Trust then applied to the court for issuance of an Order to show cause why Mr. Brotton's claim should be paid on Matrix A-1. On November 19, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3133 (Nov. 19, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on February 2, 2004. The

7. (...continued)
representation as to the level of claimant's ejection fraction.

8. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. See PTO No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807. See PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures govern Mr. Brotton's claim.

Show Cause Record is now before the court for final determination. See Audit Policies and Procedures § VI.O.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he did not have a congenital aortic valve abnormality (*i.e.*, a bicuspid aortic valve). See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of his claim, Mr. Brotton submitted a partially-completed Green Form signed by Michael L. Chaikin, M.D., in which Dr. Chaikin attests that it is "uncertain" whether claimant suffers from congenital aortic valve abnormalities. Dr. Chaikin explains that the "[a]ortic valve is calcified and distorted enough and study is not as clear as possible ... cannot for certain ascertain whether this valve is bicuspid or tricuspid." Claimant argues, based on the findings of the two attesting physicians, that "either the aortic valve is congenitally normal or ... it cannot be determined from the

relevant echocardiogram whether there is an abnormality or not." In addition, claimant argues that the Trust has the burden in proving by a preponderance of the evidence the existence of a particular medical issue when reducing Matrix Benefits from Matrix A-1 to Matrix B-1.

In response, the Trust forwarded claimant's echocardiographic study to Dr. Churchwell for a second review. Dr. Churchwell then submitted a supplemental declaration, in which he opined, in relevant part, that:

In connection with my review, I again observed heavy calcium on the posterior cusp of the aortic valve. I observed that at 266.05 on Claimant's echocardiogram tape, there is a zoomed-in short axis view of Claimant's aortic valve. Claimant's aortic valve is obviously abnormal, with significant thickening and calcification of the anterior leaflet of the valve. I determined that only two valve leaflets are visible--the anterior and posterior leaflets--which resemble in appearance, the open mouth of a fish. No third leaflet can be seen on Claimant's echocardiogram tape. Claimant's aortic valve leaflets exhibit the classic appearance of a bicuspid aortic valve in the transthoracic view.

The Trust also argues that the burden of proof is on claimant to prove that there is a reasonable medical basis for the attesting physician's representations, and that the Trust does not have a burden in disproving any of the attesting physician's findings. Finally, the Trust contends that Dr. Chaikin's inability to confirm or deny the presence of congenital aortic valve

abnormalities "emphasizes Claimant's failure to meet his burden of proof."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. As an initial matter, we reject claimant's argument that the Trust has the burden in proving by a preponderance of the evidence the existence of a particular medical condition. Specifically, the Audit Policies and Procedures state, in pertinent part, that:

For audits based, in whole or in part, on the grounds that no reasonable medical basis exists for specific answer(s) to the Audit Question(s), the Claimant shall have the burden of proving that there was a reasonable medical basis to support the material representation(s) made by the Attesting Physician in answering the Audit Question(s).

In addition, we disagree with claimant that there is a reasonable medical basis for Dr. Drabinsky's representation that claimant did not have congenital aortic valve abnormalities. In support of his claim, Mr. Brotton rests on the Green Form signed Dr. Chaikin and a letter from Dr. Drabinsky. Dr. Chaikin, however, specifically notes that he "cannot for certain ascertain whether this valve is bicuspid or tricuspid." In addition, Dr. Drabinsky notes only that "[w]hile the aortic valve commissures appear fused, this is not a bicuspid aortic valve."

Claimant did not dispute or respond to Dr. Churchwell's specific determination that his "aortic valve is obviously abnormal, with significant thickening and calcification of the

anterior leaflet of the valve Claimant's aortic valve leaflets exhibit the classic appearance of a bicuspid aortic valve in the transthoracic view." Moreover, claimant did not provide any explanation for the difference between his attesting physician's representation that Mr. Brotton did not suffer from congenital aortic valve abnormalities, including a bicuspid aortic valve, and the conclusion of Dr. Christodoulous, the reviewing cardiologist, that claimant had "[m]ild aortic stenosis with bicuspid valve." Under these circumstances, claimant has failed to meet his burden of demonstrating that there is a reasonable medical basis for his claim.

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis for finding that he did not have congenital aortic valve abnormalities. Therefore, we affirm the Trust's determination that claimant is entitled only to Matrix B-1, Level I benefits.